Complete Summary

GUIDELINE TITLE

Nonpharmacological management and health care maintenance of patients with chronic heart failure: HFSA 2006 comprehensive heart failure practice guideline.

BIBLIOGRAPHIC SOURCE(S)

Heart Failure Society of America. Nonpharmacologic management and health care maintenance in patients with chronic heart failure. J Card Fail 2006 Feb;12(1):e29-37. [92 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Heart Failure Society of America. Heart Failure Society of America (HFSA) practice guidelines. HFSA guidelines for management of patients with heart failure caused by left ventricular systolic dysfunction--pharmacological approaches. J Card Fail 1999 Dec;5(4):357-82.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

- On July 8, 2005, the U.S. Food and Drug Administration (FDA) notified healthcare professionals of updated labeling for Cialis, Levitra and Viagra to reflect a small number of post-marketing reports of sudden vision loss, attributed to NAION (non arteritic ischemic optic neuropathy), a condition where blood flow is blocked to the optic nerve. FDA advises patients to stop taking these medicines, and call a doctor or healthcare provider right away if they experience sudden or decreased vision loss in one or both eyes. Patients taking or considering taking these products should inform their health care professionals if they have ever had severe loss of vision, which might reflect a prior episode of NAION. Such patients are at an increased risk of developing NAION again. At this time, it is not possible to determine whether these oral medicines for erectile dysfunction were the cause of the loss of eyesight or whether the problem is related to other factors such as high blood pressure or diabetes, or to a combination of these problems. See the FDA Web site for more information.
- On September 27, 2005, GlaxoSmithKline (GSK) and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of changes to the Pregnancy/PRECAUTIONS section of the Prescribing Information for Paxil and

Paxil CR Controlled-Release Tablets to describe the results of a GSK retrospective epidemiologic study of major congenital malformations in infants born to women taking antidepressants during the first trimester of pregnancy. This study suggested an increase in the risk of overall major congenital malformations for paroxetine as compared to other antidepressants [OR 2.2; 95% confidence interval, 1.34-3.63]. Healthcare professionals are advised to carefully weigh the potential risks and benefits of using paroxetine therapy in women during pregnancy and to discuss these findings as well as treatment alternatives with their patients. See the FDA Web site for more information.

- On July 1, 2005, in response to recent scientific publications that report the possibility of increased risk of suicidal behavior in adults treated with antidepressants, the U.S. Food and Drug Administration (FDA) issued a Public Health Advisory to update patients and healthcare providers with the latest information on this subject. Even before the publication of these recent reports, FDA had already begun the process of reviewing available data to determine whether there is an increased risk of suicidal behavior in adults taking antidepressants. The Agency has asked manufacturers to provide information from their trials using an approach similar to that used in the evaluation of the risk of suicidal behavior in the pediatric population taking antidepressants. This effort will involve hundreds of clinical trials and may take more than a year to complete. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Chronic heart failure

GUIDELINE CATEGORY

Management

CLINICAL SPECIALTY

Cardiology
Family Practice
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations for the nonpharmacologic management and health care maintenance in patients with chronic heart failure

TARGET POPULATION

Patients with chronic heart failure

INTERVENTIONS AND PRACTICES CONSIDERED

1. Dietary instruction
2. Sodium restriction
3. Daily fluid intake restriction
4. Measurement of nitrogen balance, caloric intake, and prealbumin
5. Multivitamin-mineral supplementation
6. Document type and dose of naturoceutical products
7. Ensure continuous positive airway pressure
8. Identify treatable conditions
9. Screen for endogenous pr prolonged reactive depression
10. Nonpharmacologic techniques for stress reduction
11. Treatment for sexual dysfunction
12. Counseling regarding smoking cessation, limiting alcohol consumption, and discontinuing illicit drug usage
13. Pneumococcal vaccine and annual influenza vaccination
14. Assess for employability

Note: The following were considered, but not recommended:

- Supplemental oxygen for patients with heart failure in the absence of an underlying pulmonary disease
- Endocarditis prophylaxis with the diagnosis of heart failure alone
- Nonsteroidal anti-inflammatory drugs, including cyclooxygenase-2 inhibitors, in patients with chronic heart failure

MAJOR OUTCOMES CONSIDERED

- Patient stability
- Daily functional capacity
- Mortality

- Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Databases searched included Medline and Cochrane. In addition, the guideline developers polled experts in specific areas for data.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Level A: Randomized, Controlled, Clinical Trials
May be assigned based on results of a single trial

Level B: Cohort and Case-Control Studies
Post hoc, subgroup analysis, and meta-analysis
Prospective observational studies or registries

Level C: Expert Opinion
Observational studies – epidemiologic findings
Safety reporting from large-scale use in practice

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Heart Failure Society of America (HFSA) Guideline Committee sought resolution of difficult cases through consensus building. Written documents were essential to this process, because they provided the opportunity for feedback from all members of the group. On occasion, consensus of Committee opinion was sufficient to override positive or negative results of almost any form or prior evidence.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

"Is recommended": Part of routine care
Exceptions to therapy should be minimized.

"Should be considered": Majority of patients should receive the intervention. Some discretion in application to individual patients should be allowed.

"May be considered": Individualization of therapy is indicated

"Is not recommended": Therapeutic intervention should not be used

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The process of moving from ideas of recommendations to a final document includes many stages of evaluation and approval. Every section, once written, had a lead reviewer and 2 additional reviewers. After a rewrite, each section was assigned to another review team, which lead to a version reviewed by the Committee as a whole and then the Heart Failure Society of America (HFSA) Executive Council, representing 1 more level of expertise and experience. Out of this process emerged the final document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The strength of evidence (A, B, C) and strength of recommendations are defined at the end of the "Major Recommendations" field.

Diet and Nutrition

- Dietary instruction regarding sodium intake is recommended in all patients with heart failure (HF). Patients with HF and diabetes, dyslipidemia, or obesity should be given specific instructions regarding carbohydrate or caloric constraints. (Strength of Evidence = B)
- Dietary sodium restriction (2 to 3 g daily) is recommended for patients with the clinical syndrome of HF and preserved or depressed left ventricular ejection fraction (LVEF). Further restriction (<2 g daily) may be considered in moderate to severe HF. (Strength of Evidence = C)
- Restriction of daily fluid intake to <2 L is recommended in patients with severe hyponatremia (serum sodium <130 mEq/L) and should be considered for all patients demonstrating fluid retention that is difficult to control despite high doses of diuretic and sodium restriction. (Strength of Evidence = C)
- It is recommended that specific attention be paid to nutritional management of patients with advanced HF and unintentional weight loss or muscle wasting (cardiac cachexia). Measurement of nitrogen balance, caloric intake, and prealbumin may be useful in determining appropriate nutritional supplementation. Caloric supplementation is recommended. Anabolic steroids are not recommended for such patients. (Strength of Evidence = C)
- Patients with HF, especially those on diuretic therapy and restricted diets, should be considered for daily multivitamin-mineral supplementation to ensure adequate intake of the recommended daily value of essential nutrients. Evaluation for specific vitamin or nutrient deficiencies is rarely necessary. (Strength of Evidence = C)
- Documentation of the type and dose of naturoceutical products used by patients with HF is recommended. (Strength of Evidence = C)

  Naturoceutical use is not recommended for relief of symptomatic HF or for the secondary prevention of cardiovascular events. Patients should be instructed to avoid using natural or synthetic products containing ephedra (ma huang), ephedrine, or its metabolites because of an increase risk of mortality and morbidity. Products should be avoided that may have significant drug interactions with digoxin, vasodilators, beta-blockers, antiarrhythmic drugs, and anticoagulants. (Strength of Evidence = B)

Other Therapies

- Continuous positive airway pressure to improve daily functional capacity and quality of life is recommended in patients with HF and obstructive sleep apnea documented by approved methods of polysomnography. (Strength of Evidence = B)
- Supplemental oxygen, either at night or during exertion, is not recommended for patients with HF in the absence of an indication of underlying pulmonary disease. Patients with resting hypoxemia or oxygen desaturation during exercise should be evaluated for residual fluid overload or concomitant pulmonary disease. (Strength of Evidence = B)
- The identification of treatable conditions, such as sleep-disordered breathing, urologic abnormalities, restless leg syndrome, and depression should be considered in patients with HF and chronic insomnia. Pharmacologic aids to sleep induction may be necessary. Agents that do not risk physical dependence are preferred. (Strength of Evidence = C)

Specific Activity and Lifestyle Issues

- It is recommended that screening for endogenous or prolonged reactive depression in patients with HF be conducted following diagnosis and at periodic intervals as clinically indicated. For pharmacologic treatment, selective serotonin reuptake inhibitors are preferred over tricyclic antidepressants, because the latter have the potential to cause ventricular arrhythmias, but the potential for drug interactions should be considered. (Strength of Evidence = B)
- Nonpharmacologic techniques for stress reduction may be considered as a useful adjunct for reducing anxiety in patients with HF. (Strength of Evidence = C)
- It is recommended that treatment options for sexual dysfunction be discussed openly with both male and female patients with HF.

  The use of phosphodiasterase-5 inhibitors such as sildenafil may be considered for use for sexual dysfunction in patients with chronic stable HF. These agents are not recommended in patients taking nitrate preparations. (Strength of Evidence = C)

Health Care Maintenance Issues

- It is recommended that patients with HF be advised to stop smoking and to limit alcohol consumption to $\leq$2 standard drinks per day in men or $\leq$1 standard drink per day in women. Patients suspected of having an alcohol-induced cardiomyopathy should be advised to abstain from alcohol consumption. Patients suspected of using illicit drugs should be counseled to discontinue such use. (Strength of Evidence = B).
- Pneumococcal vaccine and annual influenza vaccination are recommended in all patients with HF in the absence of known contraindications. (Strength of Evidence = B)
- Endocarditis prophylaxis is not recommended based on the diagnosis of HF alone. Prophylaxis for dental and other procedures should be given according to standard clinical indications. (Strength of Evidence = C)
- Nonsteroidal anti-inflammatory drugs, including cyclooxygenase-2 inhibitors, are not recommended in patients with chronic HF. The risk of renal failure and fluid retention is markedly increased in the setting of reduced renal function or angiotensin-converting enzyme (ACE) inhibitor therapy. (Strength of Evidence = B)
- It is recommended that patients with new- or recent-onset HF be assessed for employability following a reasonable period of clinical stabilization. An objective assessment of functional exercise capacity is useful in this determination. (Strength of Evidence = B)
- It is recommended that patients with chronic HF who are employed and whose job description is compatible with their prescribed activity level be encouraged to remain employed, even if a temporary reduction in hours worked or task performed is required. Retraining should be considered and supported for patients with a job demanding a level of physical exertion exceeding recommended levels. (Strength of Evidence = B)

Definitions:

Strength of Evidence

Level A: Randomized, Controlled, Clinical Trials
May be assigned based on results of a single trial

Level B: Cohort and Case-Control Studies
Post hoc, subgroup analysis, and meta-analysis
Prospective observational studies or registries

Level C: Expert Opinion
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Safety reporting from large-scale use in practice

Strength of Recommendations

"Is recommended": Part of routine care
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"Should be considered": Majority of patients should receive the intervention. Some discretion in application to individual patients should be allowed.

"May be considered": Individualization of therapy is indicated

"Is not recommended": Therapeutic intervention should not be used

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations").

The recommendations are supported by randomized controlled clinical trials, cohort and case-control studies, and expert opinion.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Nonpharmacologic management may significantly impact patient stability, functional capacity, mortality, and quality of life.

POTENTIAL HARMS

- The likelihood of an adverse reaction or vitamin toxicity increases with consumption of multiple supplements, the safety and efficacy of which are not well documented.

- Tricyclic antidepressants have anticholinergic properties that increase heart rate, promote orthostatic hypotension, and alter ventricular repolarization.

CONTRAINDICATIONS

CONTRAINDICATIONS

Natural or synthetic catecholamine-like products containing ephedra (ma huang), ephedrine metabolites, or imported Chinese herbs are specifically contraindicated in heart failure (HF).

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

It must be recognized that the evidence supporting recommendations is based largely on population responses that may not always apply to individuals within the population. Therefore, data may support overall benefit of 1 treatment over another but cannot exclude that some individuals within the population may respond better to the other treatment. Thus guidelines can best serve as evidence-based recommendations for management, not as mandates for management in every patient. Furthermore, it must be recognized that trial data on which recommendations are based have often been carried out with background therapy not comparable to therapy in current use. Therefore, physician decisions regarding the management of individual patients may not always precisely match the recommendations. A knowledgeable physician who integrates the guidelines with pharmacologic and physiologic insight and knowledge of the individual being treated should provide the best patient management.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Pocket Guide/Reference Cards
Slide Presentation

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Heart Failure Society of America. Nonpharmacologic management and health care maintenance in patients with chronic heart failure. J Card Fail 2006 Feb;12(1):e29-37. [92 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 (revised 2006 Feb)

GUIDELINE DEVELOPER(S)

Heart Failure Society of America, Inc - Disease Specific Society

SOURCE(S) OF FUNDING

Heart Failure Society of America, Inc

GUIDELINE COMMITTEE

Comprehensive Heart Failure Practice Guideline Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members and reviewers from the Executive Council received no direct financial support from the Heart Failure Society of America (HFSA) or any other source for the development of the guideline. Administrative support was provided by the Heart Failure Society of America staff, and the writing of the document was performed on a volunteer basis by the Committee. Financial relationships that might represent conflicts of interest were collected for all members of the Guideline Committee and of the Executive Council, who were asked to disclose potential conflicts and recuse themselves from discussions when necessary. Current relationships are shown in Table 1.5 of the "Development and Implementation" companion document (see the "Availability of Companion Documents" field).

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Heart Failure Society of America. Heart Failure Society of America (HFSA) practice guidelines. HFSA guidelines for management of patients with heart failure caused by left ventricular systolic dysfunction--pharmacological approaches. J Card Fail 1999 Dec;5(4):357-82.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Heart Failure Society of America, Inc. Web site.

Print copies: Available from the Heart Failure Society of America, Inc., Court International - Suite 240 S, 2550 University Avenue West, Saint Paul, Minnesota 55114; Phone: (651) 642-1633

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Heart Failure Society of America. Executive summary: HFSA 2006 comprehensive heart failure practice guideline. J Card Fail 2006 Feb;12(1):10-38.
- Heart Failure Society of America. Development and implementation of a comprehensive heart failure practice guideline. J Card Fail 2006 Feb;12(1):e3-9.
- Heart Failure Society of America. Conceptualization and working definition of heart failure. J Card Fail 2006 Feb;12(1):e10-11.

  Electronic copies: Available from the Heart Failure Society of America, Inc. Web site.

- PowerPoint slides. HFSA 2006 comprehensive heart failure guideline.

  Electronic copies: Available from the Heart Failure Society of America, Inc. Web site.

The following is also available:

- Heart Failure Society of America. Pocket guide. HFSA 2006 comprehensive heart failure practice guideline.

Electronic copies: Not available at this time.

Print copies: Available from the Heart Failure Society of America, Inc., Court International - Suite 240 South, 2550 University Avenue West, Saint Paul, Minnesota 55114; Phone: (651) 642-1633

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on July 31, 2006. The information was verified by the guideline developer on August 10, 2006.

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